



AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
<http://www.alp-bfs.com>

Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Artificial Tears

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contract manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 - 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349**. The line consists of the following:

<u>PRODUCT NAME</u>	<u>ACTIVE INGREDIENT</u>
Artificial Tears	Polyvinyl Alcohol (a demulcent) Povidone (a demulcent)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in **21 CFR 349**.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "**Over-The-Counter Human Drugs; Labeling Requirements**" for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel.

98N-0337

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In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop Container opening instructions Statements such as this also must appear on the outside package.

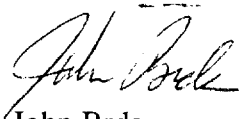
As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will acquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.



John Brda
Regulatory Affairs Manager


c Al Rothchild

.5 Oz. Artificial Tear Eye Drops

Logo

Sterile

**Artificial
Tears**



• Lubricant Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of burning and irritation due to dryness of the eye.

DIRECTIONS: Instill 1 or 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyvinyl Alcohol, 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEDS-13-0000

1 Oz. Artificial Tears Eye Drops

Logo

**Artificial
Tears**

• Lubricant Eye Drops

1 fl. oz. (30 mL)

INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyvinyl Alcohol 1.4% and Povidone 0.5%

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

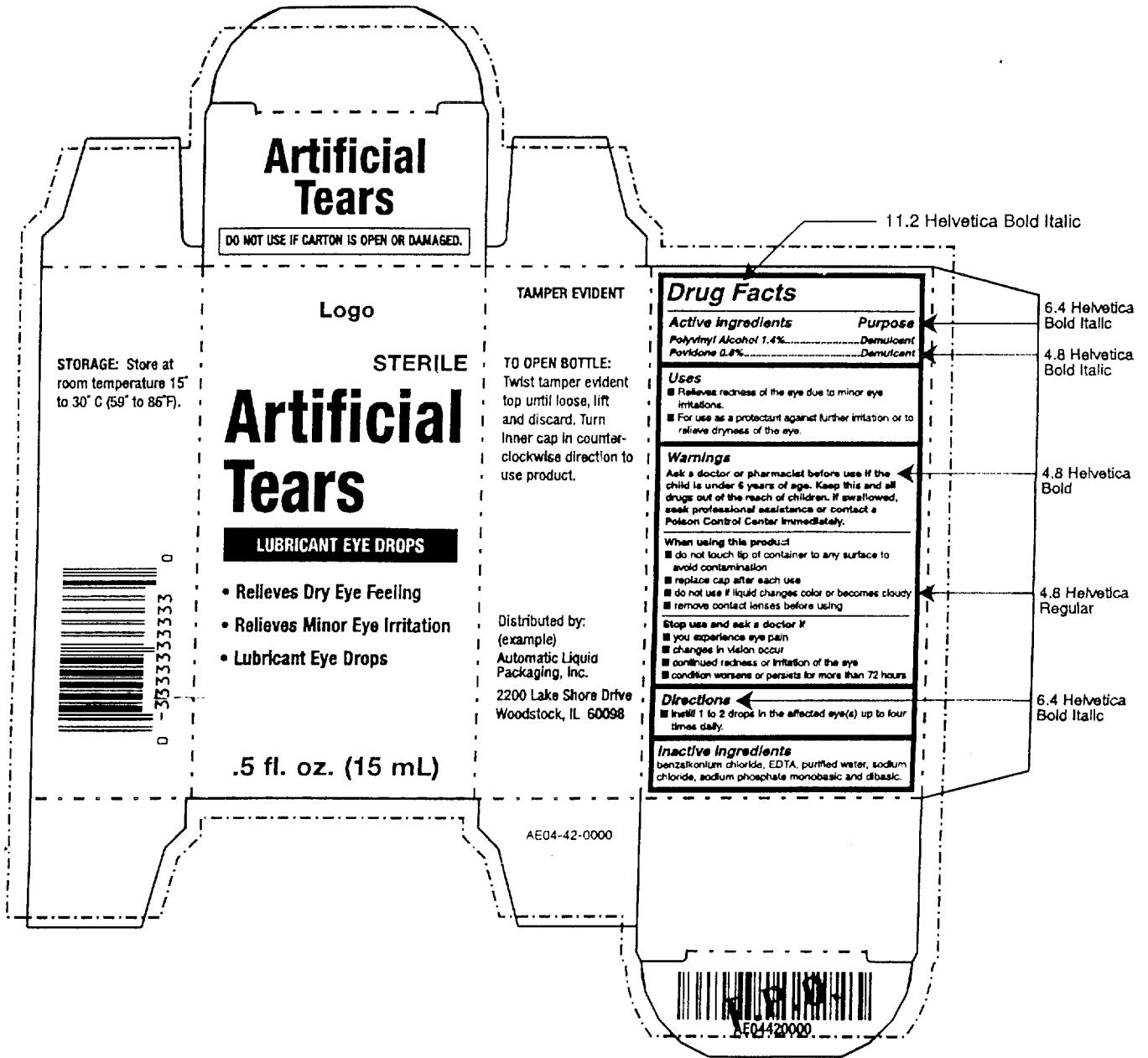
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

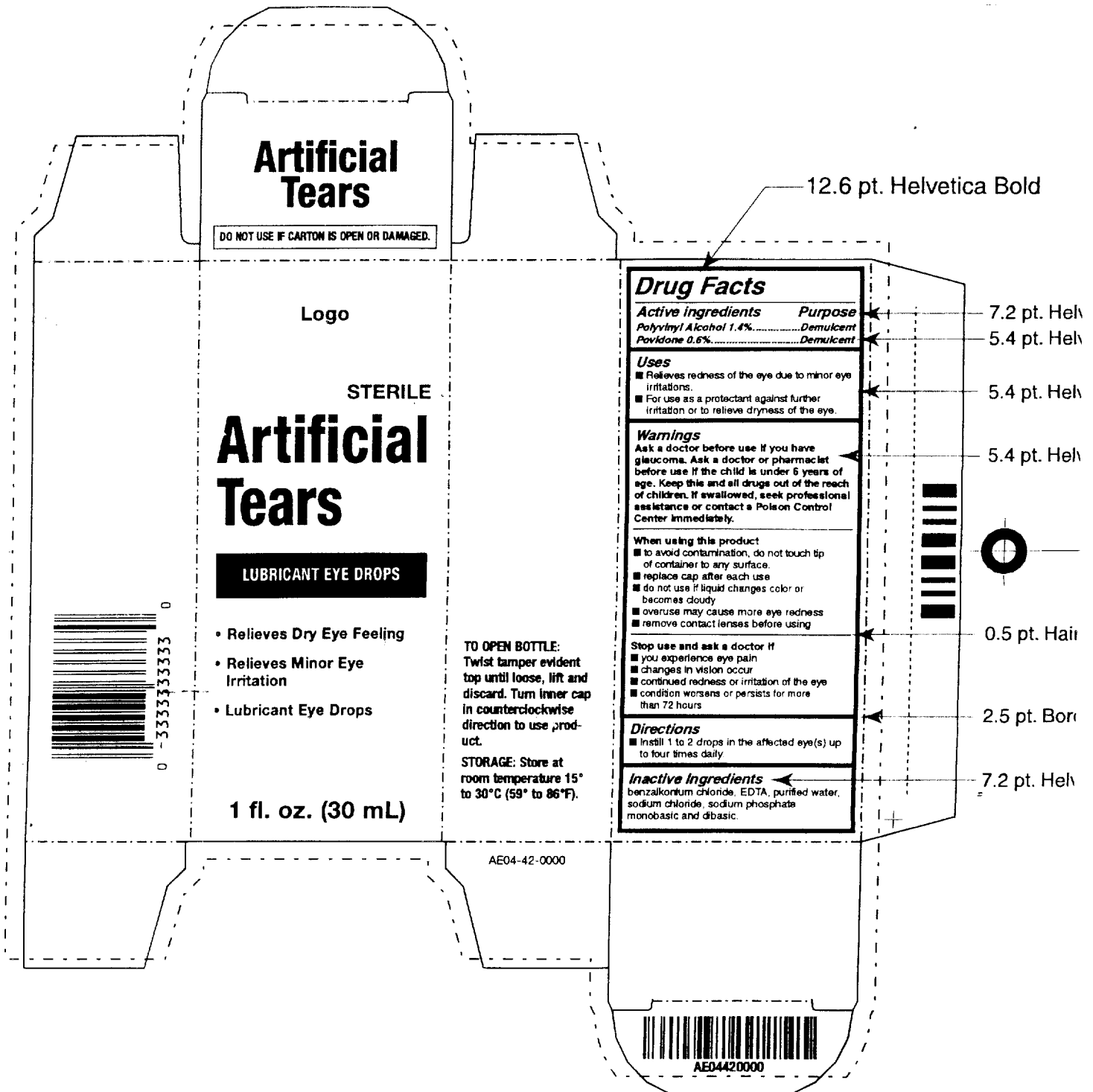
Discontinued by or Manufactured by:

AZ05-13-0000

.5 Oz. Artificial Tears



1 Oz. Artificial Tears



.5 Oz. Artificial Tear Eye Drops

Logo

Sterile

**Artificial
Tears**

• Lubricant Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of burning and irritation due to dryness of the eye.

DIRECTIONS: Instill 1 or 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyvinyl Alcohol, 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEOS-13-0000

1 Oz. Artificial Tears Eye Drops

Logo

**Artificial
Tears**

• Lubricant Eye Drops

1 fl. oz. (30 mL)

INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polystyrl Alcohol 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

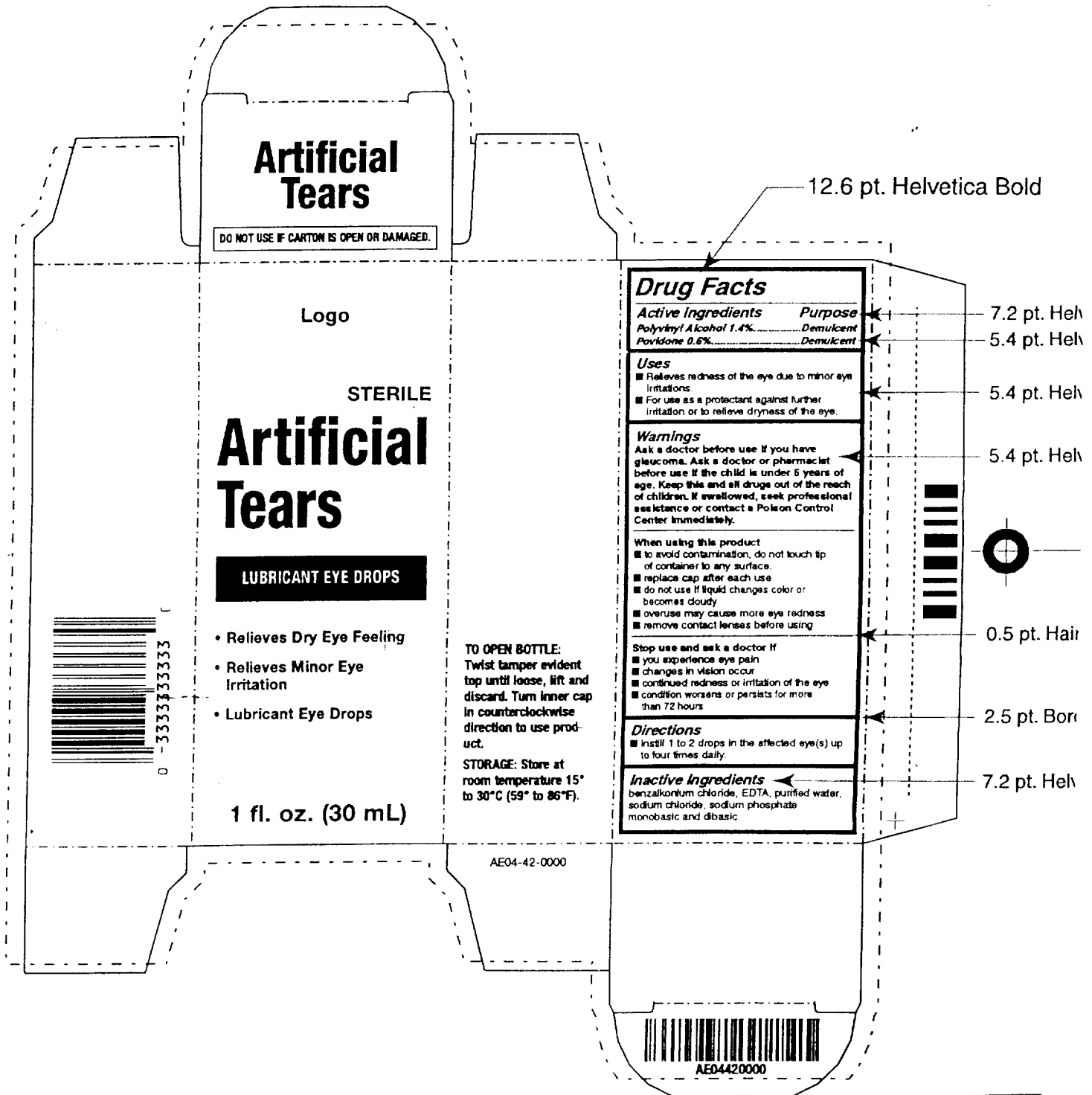
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by:

AE05-13-0000

1 Oz. Artificial Tears



.5 Oz. Artificial Tear Eye Drops

Logo

Sterile

**Artificial
Tears**

• Lubricant Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of burning and irritation due to dryness of the eye.

DIRECTIONS: Instill 1 or 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyvinyl Alcohol, 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEOS 13 0000

1 Oz. Artificial Tears Eye Drops

Logo

**Artificial
Tears**

[REDACTED]

Lubricant Eye Drops

1 fl. oz. (30 mL)

INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) as needed.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyvinyl Alcohol, 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

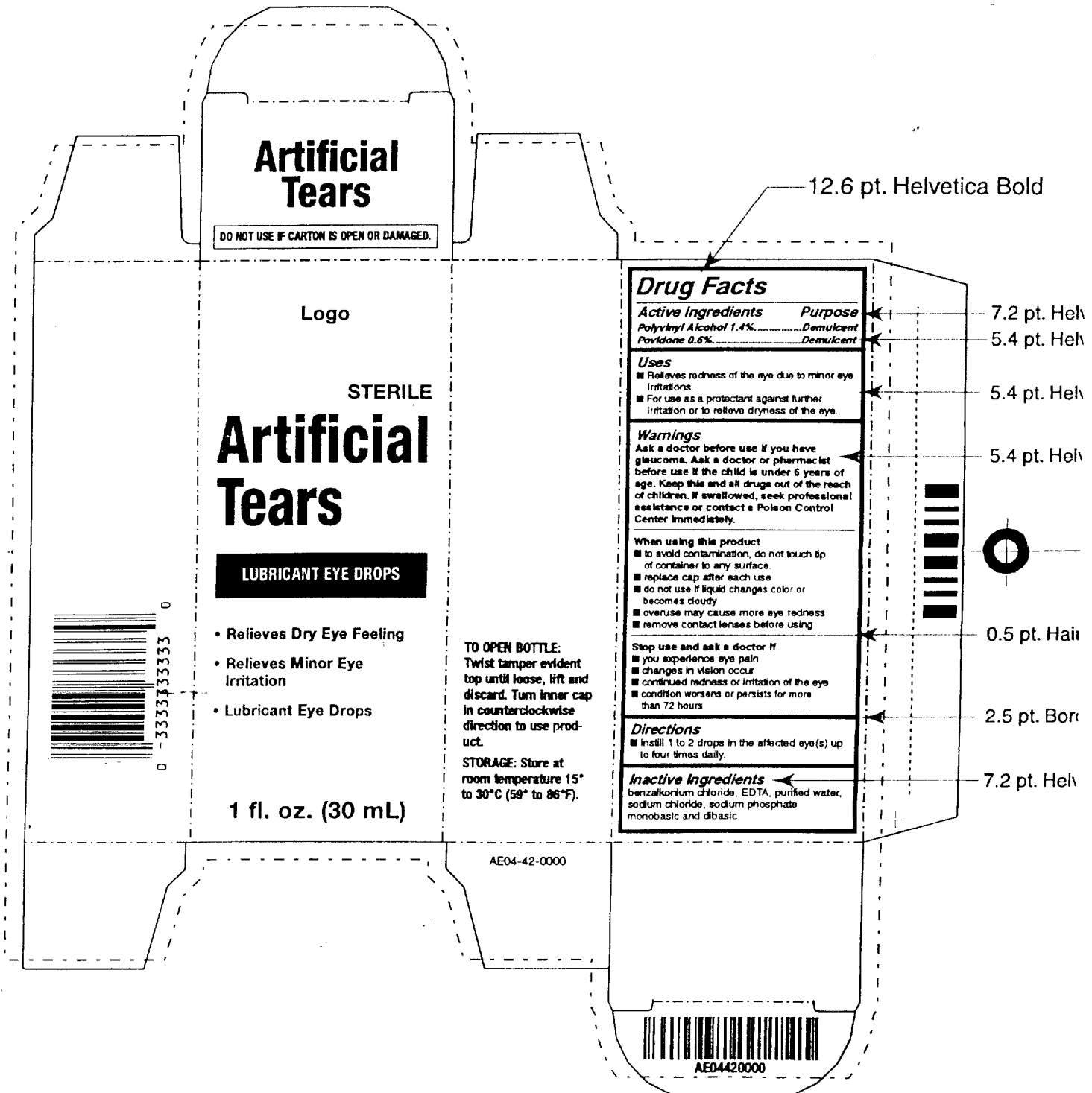
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Dist. by or Manufactured by:

AEOS-13-0000

1 Oz. Artificial Tears



EYEDROPS .5 OZ. AND 1 OZ.

FIRST AID/SAFETY MARKET

.5 oz. Tetra

MIAMI MARKET-EXPORT

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

.5 oz. Artificial Tears

AARP Retired Persons Pharmacy

1 oz. F-455 PVA Lubricant Eyedrops

1 oz. F-707 PVA Povidone Eyedrops

1 oz. R-450 Eyedrops

1 oz. Extra Eyedrops

1 oz. Relief Eyedrops

ALBERTSONS

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

ALPINE DISTRIBUTORS

.5 oz. Tetra Eyedrops

AMERICAN DRUG

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

AMES

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

.5 oz. Artificial Tears

BRUNOS

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

CERTIFIED GROCERS

. 5 oz. Tetra Eyedrops

DEMOULAS

.5 oz. Tetra Eyedrops
.5 Extra Eyedrops

DUANE READE

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

FEDERATED FOODS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

GENOVESE

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

GRANDALL

. 5 oz. Tetra Eyedrops

GRANDPAS

.5 oz. Tetra Eyedrops

GRAND UNION

.5 oz. Tetra Eyedrops

HARMON DISCOUNT

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

HARRIS TEETER

1 oz. Tetra Eyedrops
1 oz. Relief Eyedrops

KROGER/PEYTON

1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

LONGS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears
1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

MARSH

.5 oz. Tetra Eyedrops

MCCLANE/CVP

.5 oz. Tetra Eyedrops

NASH FINCH

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Artificial Tears

PAHTMARK

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

PUBLIX

.5 oz. Tetra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

REPUBLIC DRUGS

.5 oz. Tetra Eyedrops

RITE AID

1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

SAFEWAY/VONS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Tetra Eyedrops

SHOPKO

.5 oz. Tetra Eyedrops
.5 oz. Artificial Tears

SUPERMARKET SERVICES

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

VALUE STAR

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

WALGREENS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

WINN DIXIE

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears